where American Indian and Alaska Native (AI/AN) programs are located. We are convening the OHS Tribal Consultations in conjunction with other Tribal Leader events in order to minimize the financial and travel burden for participants. The sessions in Phoenix, Arizona, and Billings, Montana, are being held in conjunction with the HHS 2012 Regional Tribal Consultation Sessions. We will schedule additional consultations around the country for later in the year.

The agenda for the scheduled OHS Tribal Consultations will be organized around the statutory purposes of Head Start Tribal Consultations related to meeting the needs of AI/AN children and families, taking into consideration funding allocations, distribution formulas, and other issues affecting the delivery of Head Start services in their geographic locations. In addition, OHS will share actions taken and in progress to address the issues and concerns raised in 2011 OHS Tribal Consultations.

Tribal leaders and designated representatives interested in submitting written testimony or proposing specific agenda topics for these Consultation Sessions should contact Camille Loya at *Camille.Loya@acf.hhs.gov.* Proposals must be submitted at least three days in advance of the session and should include a brief description of the topic area, along with the name and contact information of the suggested presenter.

The Consultation Sessions will be conducted with elected or appointed leaders of Tribal Governments and their designated representatives [42 U.S.C.9835, Section 640(l)(4)(A)]. Designees must have a letter from the Tribal Government authorizing them to represent the tribe. The letter should be submitted at least three days in advance of the Consultation Session to Camille Loya at (202) 205–9721 (fax). Other representatives of tribal organizations and Native nonprofit organizations are welcome to attend as observers.

A detailed report of each Consultation Session will be prepared and made available within 90 days of the Consultation Session to all Tribal Governments receiving funds for Head Start and Early Head Start programs. Tribes wishing to submit written testimony for the report should send testimony to Camille Loya at *Camille.Loya@acf.hhs.gov* either prior to the Consultation Session or within 30 days after the meeting.

Oral testimony and comments from the Consultation Sessions will be summarized in each report without attribution, along with topics of concern and recommendations. Hotel and logistical information for all Consultation Sessions has been sent to tribal leaders via email and posted on the Head Start Resource Center Web site at *http://www.headstartresourcecenter.org.*

Dated: February 28, 2012.

Yvette Sanchez Fuentes,

Director, Office of Head Start.

[FR Doc. 2012–5438 Filed 3–5–12; 8:45 am]

BILLING CODE 4184–40–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0169]

Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: Under the Food and Drug Administration Modernization Act of 1997 (Modernization Act), the Food and Drug Administration (FDA) is required to report annually in the **Federal Register** on the status of postmarketing requirements and commitments required of, or agreed upon by, holders of approved drug and biological products. This notice is the Agency's report on the status of the studies and clinical trials that applicants have agreed to, or are required to, conduct.

FOR FURTHER INFORMATION CONTACT: Meg Pease-Fye, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4156, Silver Spring, MD 20993–0002, 301–796–0700; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Modernization Act

Section 130(a) of the Modernization Act (Pub. L. 105–115) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding a new provision requiring reports of certain postmarketing studies, including clinical trials, for human drug and biological products (section 506B of the FD&C Act (21 U.S.C. 356b)). Section 506B of the FD&C Act provides FDA with additional authority to monitor the progress of a postmarketing study or clinical trial that an applicant has been required to, or has agreed to, conduct by requiring the applicant to submit a report annually providing information on the status of the postmarketing study/clinical trial. This report must also include reasons, if any, for failure to complete the study/clinical trial. These studies and clinical trials are intended to further define the safety, efficacy, or optimal use of a product, and therefore play a vital role in fully characterizing the product.

Under the Modernization Act, commitments to conduct postmarketing studies or clinical trials included both studies/clinical trials that applicants agreed to conduct, as well as studies/clinical trials that applicants were required to conduct under FDA regulations.[1]

B. The Food and Drug Administration Amendments Act of 2007

On September 27, 2007, the President signed Public Law 110–85, the Food and Drug Administration Amendments Act of 2007 (FDAAA). Section 901, in Title IX of FDAAA, created a new section 505(o) of the FD&C Act authorizing FDA to require certain studies and clinical trials for human drug and biological products approved under section 505 of the FD&C Act or section 351 of the Public Health Service Act. Under FDAAA, FDA has been given additional authority to require applicants to conduct and report on postmarketing studies and clinical trials to assess a known serious risk, assess signals of serious risk, or identify an unexpected serious risk related to the use of a product. This new authority became effective on March 25, 2008. FDA may now take enforcement action against applicants who fail to conduct studies and clinical trials required under FDAAA, as well as studies and clinical trials required under FDA regulations (see sections 505(o)(1), 502(z), and 303(f)(4) of the FD&C Act (21 U.S.C. 355(o)(1), 352(z), and 333(f)(4))).

Although regulations implementing the Modernization Act postmarketing authorities use the term ''postmarketing commitment'' to refer to both required

[1] Before passage of the Food and Drug Administration Amendments Act of 2007 (FDAAA), FDA could require postmarketing studies and clinical trials under the following circumstances: To verify adn describe clinical benefit for a human drug approved in accordance with the accelerated approval provisions in section 506(b)(2)(A) of the FD&C Act (21 CFR 314.510 and 601.41); for a drug approved on the basis of animal efficacy data because human efficacy trials are not ethical or feasible (21 CFR 314.610(b)(1) and 601.91(b)(1)): and for marketed drugs that not adequately labeled for children under section 505B of the FD&C Act (Pediatric Research Equity Act (21 U.S.C. 355c; Pub. L. 108–155)).

studies and studies applicants agree to conduct, in light of the new authorities enacted in FDAAA, FDA has decided it is important to distinguish between enforceable postmarketing requirements and unenforceable postmarketing commitments. Therefore, in this notice and report, FDA refers to studies/clinical trials that an applicant is required to conduct as ''postmarketing requirements'' (PMRs) and studies/clinical trials that an applicant agrees to but is not required to conduct as ''postmarketing commitments'' (PMCs). Both are addressed in this notice and report.

C. FDA's Implementing Regulations

On October 30, 2000 (65 FR 64607), FDA published a final rule implementing section 130 of the Modernization Act. This rule modified the annual report requirements for new drug applications (NDAs) and abbreviated new drug applications (ANDAs) by revising § 314.81(b)(2)(vii) (21 CFR 314.81(b)(2)(vii)). The rule also created a new annual reporting requirement for biologics license applications (BLAs) by establishing § 601.70 (21 CFR 601.70). The rule described the content and format of the annual progress report, and clarified the scope of the reporting requirement and the timing for submission of the annual progress reports. The rule became effective on April 30, 2001. The regulations apply only to human drug and biological products approved under NDAs, ANDAs, and BLAs. They do not apply to animal drugs or to biological products regulated under the medical device authorities.

The reporting requirements under §§ 314.81(b)(2)(vii) and 601.70 apply to PMRs and PMCs made on or before the enactment of the Modernization Act (November 21, 1997), as well as those made after that date. Therefore, studies and clinical trials required under FDAAA are covered by the reporting requirements in these regulations.

Sections 314.81(b)(2)(vii) and 601.70 require applicants of approved drug and biological products to submit annually a report on the status of each clinical safety, clinical efficacy, clinical pharmacology, and nonclinical toxicology study/clinical trial either required by FDA or that they have committed to conduct, either at the time of approval or after approval of their NDA, ANDA, or BLA. The status of PMCs concerning chemistry, manufacturing, and production controls and the status of other studies/clinical trials conducted on an applicant's own initiative are not required to be reported under §§ 314.81(b)(2)(vii) and 601.70 and are not addressed in this report. It should be noted, however, that applicants are required to report to FDA on these commitments made for NDAs and ANDAs under § 314.81(b)(2)(viii). Furthermore, section 505(o)(3)(E) of the FD&C Act, as amended by FDAAA, requires that applicants report periodically on the status of each required study/clinical trial and each study/clinical trial ''otherwise undertaken * * * to investigate a safety issue * * *.''

According to the regulations, once a PMR has been required, or a PMC has been agreed upon, an applicant must report on the progress of the PMR/PMC on the anniversary of the product's approval until the PMR/PMC is completed or terminated and FDA determines that the PMR/PMC has been fulfilled or that the PMR/PMC is either no longer feasible or would no longer provide useful information. The annual progress report must include a description of the PMR/PMC, a schedule for completing the PMR/PMC, and a characterization of the current status of the PMR/PMC. The report must also provide an explanation of the PMR/PMC status by describing briefly the progress of the PMR/PMC. A PMR/PMC schedule is expected to include the actual or projected dates for the following: (1) Submission of the final protocol to FDA, (2) completion of the study/clinical trial, and (3) submission of the final report to FDA. The status of the PMR/PMC must be described in the annual report according to the following definitions:

- *Pending:* The study/clinical trial has not been initiated (i.e., no subjects have been enrolled or animals dosed), but does not meet the criteria for delayed (i.e., the original projected date for initiation of subject accrual or initiation of animal dosing has not passed);
- *Ongoing:* The study/clinical trial is proceeding according to or ahead of the original schedule;
- *Delayed:* The study/clinical trial is behind the original schedule;
- *Terminated:* The study/clinical trial was ended before completion, but a final report has not been submitted to FDA; or
- *Submitted:* The study/clinical trial has been completed or terminated, and a final report has been submitted to FDA.

Databases containing information on PMRs/PMCs are maintained at the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER).

II. Summary of Information From Postmarketing Status Reports

This report, published to fulfill the annual reporting requirement under the Modernization Act, summarizes the status of PMRs and PMCs as of September 30, 2011. If a requirement or commitment did not have a schedule, or a postmarketing progress report was not received in the previous 12 months, the PMR/PMC is categorized according to the most recent information available to the Agency.[2]

Information in this report covers any PMR/PMC that was made, in writing, at the time of approval or after approval of an application or a supplement to an application, including PMRs required under FDAAA (section 505(o)(3) of the FD&C Act), PMRs required under FDA regulations (e.g., PMRs required to demonstrate clinical benefit of a product following accelerated approval (see footnote 1 of this document)), and PMCs agreed to by the applicant.

Information summarized in this report includes the following: (1) The number of applicants with open (uncompleted) PMRs/PMCs, (2) the number of open PMRs/PMCs, (3) the status of open PMRs/PMCs as reported in § 314.81(b)(2)(vii) or § 601.70 annual reports, (4) the status of concluded PMRs/PMCs as determined by FDA, and (5) the number of applications with open PMRs/PMCs for which applicants did not submit an annual report within 60 days of the anniversary date of U.S. approval.

Additional information about PMRs/PMCs submitted by applicants to CDER and CBER is provided on FDA's Web site at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/default.htm*.'' Neither the Web site nor this notice include information about PMCs concerning chemistry, manufacturing, and controls. It is FDA policy not to post information on the Web site until it has been reviewed for accuracy. Numbers published in this notice cannot be compared with the numbers resulting from searches of the Web site because this notice incorporates totals for all PMRs/PMCs in FDA databases, including PMRs/PMCs undergoing review for accuracy. In addition, the report in this notice will be updated annually while the Web site is updated quarterly (i.e., in January, April, July, and October).

[2] Although the data included in this report do not include a summary of reports that applicants have failed to file by their due date, the Agency notes that it may take appropriate regulatory action in the event reports are not filed on a timely basis.

Many applicants have more than one approved product and for many products there is more than one PMR or PMC. Specifically, there were 175 unique applicants with 198 NDAs/ANDAs that had open PMRs/PMCs. There were 72 unique applicants with 99 BLAs that had open PMRs/PMCs.

Annual status reports are required to be submitted for each open PMR/PMC within 60 days of the anniversary date of U.S. approval of the original application. In fiscal year 2011 (FY11), 21 percent (43/208) of NDA/ANDA and 41 percent (41/99) of BLA annual status reports were not submitted within 60 days of the anniversary date of U.S. approval of the original application. Of the annual status reports due but not submitted on time, 100 percent of the NDA/ANDA and 56 percent (23/41) of the BLA reports were submitted before the close of FY11 (September 30, 2011).

Most PMRs are progressing on schedule (87 percent for NDAs/ANDAs; 88 percent for BLAs). Most PMCs are also progressing on schedule (80 percent for NDAs/ANDAs; 75 percent for BLAs). Most of the PMCs that are currently listed in the database were developed before the postmarketing requirements section of FDAAA took effect.[3]

III. About This Report

This report provides six separate summary tables. The tables in this document distinguish between PMRs and PMCs and between on-schedule and off-schedule PMRs and PMCs according to the original schedule milestones. On-schedule PMRs/PMCs are categorized as pending, ongoing, or submitted. Off-schedule PMRs/PMCs that have missed one of the original milestone dates are categorized as delayed or terminated. The tables include data as of September 30, 2011.

Table 1 of this document provides an overall summary of the data on all PMRs and PMCs. Tables 2 and 3 of this document provide detail on PMRs. Table 2 of this document provides additional detail on the status of on-schedule PMRs.

Table 1 of this document shows that most PMRs (87 percent for NDAs/ANDAs and 88 percent for BLAs) and most PMCs (80 percent for NDAs/ANDAs and 75 percent for BLAs) are on schedule. Overall, of the PMRs that are pending (*i.e.* , have not been initiated), 92 percent were created within the past 3 years. Table 2 of this document shows that 49 percent of pending PMRs for drug and biological products are in response to the Pediatric Research and Equity Act (PREA), under which FDA requires sponsors to study new drugs, when appropriate, for pediatric populations. Under section 505B(a)(3) of the FD&C Act, the initiation of these studies generally is deferred until required safety information from other studies has first been submitted and reviewed. PMRs for products approved under the animal efficacy rule (21 CFR 314.600 for drugs; 21 CFR 601.90 for biological products) can be conducted only when the product is used for its indication as a counterterrorism measure. In the absence of a public health emergency, these studies/clinical trials will remain pending indefinitely. The next largest category of pending PMRs for drug and biological products (49 percent) comprises those studies/clinical trials required by FDA under FDAAA, which became effective on March 25, 2008.

Table 3 of this document provides additional detail on the status of off-schedule PMRs. The majority of off-schedule PMRs (which account for 13 percent of the total for NDAs/ANDAs and 12 percent for BLAs) are delayed according to the original schedule milestones (98 percent (83/85) for NDAs/ANDAs; 95 percent (20/21) for BLAs). In certain situations, the original schedules may have been adjusted for unanticipated delays in the progress of the study/clinical trial (*e.g.* , difficulties with subject enrollment in a trial for a marketed drug or need for additional time to analyze results). In this report, study/clinical trial status reflects the status in relation to the original study/clinical trial schedule regardless of whether FDA has acknowledged that additional time may be required to complete the study/clinical trial.

Tables 4 and 5 of this document provide additional detail on the status of PMCs. Table 4 of this document provides additional detail on the status of on-schedule PMCs. Pending PMCs comprise 48 percent (141/295) of the on-schedule NDA/ANDA PMCs and 39 percent (81/209) of the on-schedule BLA PMCs.

Table 5 of this document provides additional details on the status of off-schedule PMCs. The majority of off-schedule PMCs (which account for 20 percent for NDAs/ANDAs and 25 percent for BLAs) are delayed according to the original schedule milestones (93 percent (69/74) for NDAs/ANDAs; 97 percent (69/71) for BLAs). As noted previously in this document, this report reflects the original due dates for study/clinical trial results and does not reflect discussions between the Agency and the sponsor regarding studies/clinical trials that may require more time for completion.

Table 6 of this document provides details about PMRs and PMCs that were concluded in the previous year. The majority of concluded PMRs and PMCs were fulfilled (70 percent of NDA/ANDA PMRs and 84 percent of BLA PMRs; 85 percent of NDA/ANDA PMCs and 80 percent of BLA PMCs).

TABLE 1—SUMMARY OF POSTMARKETING REQUIREMENTS AND COMMITMENTS

[Numbers as of September 30, 2011]

	NDA/ANDA (percent of total PMR or percent of total PMC)	BLA (percent of total PMR or percent of total PMC) [1]
Number of open PMRs	675	176
On-schedule open PMRs (see table 2 of this document)	590 (87%)	155 (88%)
Off-schedule open PMRs (see table 3 of this document)	85 (13%)	21 (12%)
Number of open PMCs	369	280
On-schedule open PMCs (see table 4 of this document)	295 (80%)	209 (75%)

[3] There are existing PMCs established before FDAAA that might meet current FDAAA standards for required safety studies/clinical trials under section 505(o)(3)(B) of the FD&C Act. Under section 505(o)(3)(c) of the FD&C Act, the Agency may convert pre-existing PMCs into PMRs if it becomes aware of new safety information.

TABLE 1—SUMMARY OF POSTMARKETING REQUIREMENTS AND COMMITMENTS—Continued

[Numbers as of September 30, 2011]

	NDA/ANDA (percent of total PMR or percent of total PMC)	BLA (percent of total PMR or percent of total PMC) [1]
Off-schedule open PMCs (see table 5 of this document)	74 (20%)	71 (25%)

[1] On October 1, 2003, FDA completed a consolidation of certain therapeutic products formerly regulated by CBER into CDER. Consequently, CDER now reviews many BLAs. Fiscal year statistics for postmarketing requirements and commitments for BLAs reviewed by CDER are included in BLA totals in this table.

TABLE 2—SUMMARY OF ON-SCHEDULE POSTMARKETING REQUIREMENTS

[Numbers as of September 30, 2011]

On-Schedule open PMRs	NDA/ANDA (percent of Total PMR)	BLA (percent of total PMR) [1]
Pending (by type):		
Accelerated approval	8	1
PREA [2]	238	34
Animal efficacy [3]	1	0
FDAAA safety (since March 25, 2008)	199	72
Total	446 (66%)	107 (61%)
Ongoing:		
Accelerated approval	13	9
PREA [2]	35	5
Animal efficacy [3]	0	0
FDAAA safety (since March 25, 2008)	41	23
Total	89 (13%)	37 (21%)
Submitted:		
Accelerated approval	3	2
PREA [2]	24	4
Animal efficacy [3]	0	0
FDAAA safety (since March 25, 2008)	28	5
Total	55 (8%)	11 (6%)
Combined total	590 (87%)	155 (88%)

[1] See note 1 for table 1 of this document.

[2] Many PREA studies have a pending status. PREA studies are usually deferred because the product is ready for approval in adults. Initiation of these studies also may be deferred until additional safety information from other studies has first been submitted and reviewed.

[3] PMRs for products approved under the animal efficacy rule (21 CFR 314.600 for drugs; 21 CFR 601.90 for biological products) can be conducted only when the product is used for its indication as a counterterrorism measure. In the absence of a public health emergency, these studies/clinical trials will remain pending indefinitely.

TABLE 3—SUMMARY OF OFF-SCHEDULE POSTMARKETING REQUIREMENTS

[Numbers as of September 30, 2011]

Off-Schedule open PMRs	NDA/ANDA (percent of total PMR)	BLA (percent of total PMR) [1]
Delayed:		
Accelerated approval	5	2
PREA	64	12
Animal efficacy	1	0
FDAAA safety (since March 25, 2008)	13	6
Total	83 (12%)	20 (11%)
Terminated	2 (0.3%)	1 (0.6%)
Combined total	85 (13%)	21 (12%)

[1] See note 1 for table 1 of this document.

TABLE 4—SUMMARY OF ON-SCHEDULE POSTMARKETING COMMITMENTS

[Numbers as of September 30, 2011]

On-Schedule open PMCs	NDA/ANDA (percent of total PMC)	BLA (percent of total PMC) [1]
Pending	141 (38%)	81 (29%)
Ongoing	77 (21%)	72 (26%)
Submitted	77 (21%)	56 (20%)
Combined total	295 (80%)	209 (75%)

[1] See note 1 for table 1 of this document.

TABLE 5—SUMMARY OF OFF-SCHEDULE POSTMARKETING COMMITMENTS

[Numbers as of September 30, 2011]

Off-Schedule open PMCs	NDA/ANDA (percent of total PMC)	BLA (percent of total PMC) [1]
Delayed	69 (19%)	69 (25%)
Terminated	5 (1%)	2 (0.7%)
Combined total	74 (20%)	71 (25%)

[1] See note 1 for table 1 of this document.

TABLE 6—SUMMARY OF CONCLUDED POSTMARKETING REQUIREMENTS AND COMMITMENTS

[October 1, 2010 to October 1, 2011]

	NDA/ANDA (percent of total)	BLA (percent of total) [1]
Concluded PMRs:		
Requirement met (fulfilled)	55 (70%)	16 (84%)
Requirement not met (released and new revised requirement issued)	21 (27%)	0 (0%)
Requirement no longer feasible or product withdrawn (released)	3 (4%)	3 (16%)
Total	79	19
Concluded PMCs:		
Commitment met (fulfilled)	109 (85%)	44 (80%)
Commitment not met (released and new revised requirement/commitment issued)	12 (9%)	2 (4%)
Commitment no longer feasible or product withdrawn (released)	7 (5%)	9 (16%)
Total	128	55

[1] See note 1 for table 1 of this document.

Dated: February 28, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–5302 Filed 3–5–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0788]

Pilot Program for Early Feasibility Study Investigational Device Exemption Applications; Termination of Acceptance of Nominations and Extending the Duration of the Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the termination of the acceptance of nominations for the Early Feasibility Study Investigational Device Exemption (IDE) Applications pilot program. This program allowed the submission of nominations from sponsors of innovative device technologies to participate in a pilot program for early feasibility study IDE applications. FDA is also announcing that the duration of the pilot program is extended to May 8, 2013, for sponsors that have already been accepted for the program.

DATES: This notice is effective March 6, 2012.

FOR FURTHER INFORMATION CONTACT: Sheila Brown, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1676, Silver Spring, MD 20993–0002, 301–796–5640.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 10, 2011 (76 FR 70150), FDA announced the availability of a draft guidance entitled ''Investigational Device Exemptions (IDE) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies.'' This guidance document is intended to facilitate early feasibility studies of medical devices, using appropriate risk mitigation strategies, under the IDE requirements. Simultaneous with the publication of the draft guidance, FDA also announced an Early Feasibility Study IDE Pilot Program (76 FR 70152, November 10, 2011) intended to collect